

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

IN RE: '318 PATENT INFRINGEMENT LITIGATION ) C.A. No. 05-356 (KAJ)  
) (consolidated)  
)  
)

**MYLAN PHARMACEUTICALS INC.'S AND MYLAN LABORATORIES INC.'S  
RESPONSES AND OBJECTIONS TO PLAINTIFFS'  
NOTICE OF DEPOSITION UNDER FED. R. CIV. P. 30(b)(6)  
(with noticed deposition date of March 15, 2006)**

Defendants Mylan Pharmaceuticals Inc. and Mylan Laboratories Inc. (collectively, "Mylan"), pursuant to Federal Rules of Civil Procedure 26 and 30, hereby submit their Responses and Objections to the Notice of Deposition Under Fed. R. Civ. P. 30(b)(6) served by Plaintiffs, having a noticed deposition date of March 15, 2006.

## OBJECTIONS APPLICABLE TO ALL DEPOSITION TOPICS

1. Mylan objects to the multiple Notices of Deposition Under Fed. R. Civ. P. 30(b)(6) served by Plaintiffs to Mylan.
2. Mylan objects to the extent any Topic is directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. Similarly, Mylan objects to the extent that any Topic seeks testimony or information concerning infringement/non-infringement. The Defendants have stipulated to infringement, in the event that the patent-in-suit is found valid and enforceable, and therefore infringement/non-infringement is no longer at issue in this litigation. Plaintiffs furthermore agreed in the Stipulation Not to Contest Infringement (“Stipulation”) that they “will not seek discovery from Defendants relating solely to the issue of infringement of the ‘318 patent.” At a minimum,

Plaintiffs should re-issue any Notice of Deposition to Mylan under Fed. R. Civ. P. 30(b)(6) pursuant to the Court's recent ruling on willfulness and the parties' Stipulation.

3. Mylan objects to the Topics set forth by Plaintiffs on the grounds that certain Topics seek testimony or information protected by the attorney-client privilege, the attorney work product doctrine, and/or other applicable privileges.

4. Mylan objects to Plaintiffs' Topics to the extent that they purport to impose obligations beyond those imposed by the Federal Rules of Civil Procedure and/or the Local Civil Rules of this Court.

5. Mylan objects to Plaintiffs' Topics to the extent that the burden or expense of the proposed discovery outweighs its likely benefit, taking into account the needs of the case, the parties' resources, the importance of the issues at stake in the litigation, and the importance of the proposed discovery in resolving the issues. *See* FED. R. CIV. P. 26(b)(2)(iii).

6. Mylan objects to Plaintiffs' definitions and instructions to the extent that they (i) change the common meaning of the English language with regard to any word or phrase; (ii) alter the scope of discovery, and purport to impose obligations beyond those imposed, under the Federal Rules of Civil Procedure and/or the Local Civil Rules of this Court; and/or (iii) define terms differently than such terms are defined under the Federal Rules of Civil Procedure and/or the common law. Mylan also objects to the definition that Plaintiffs have provided for terms used in these Topics to the extent that they are overly broad, argumentative, prejudicial, improper, incorrect, vague and/or ambiguous. Specific explanations of the objections will be provided.

7. Mylan objects to Plaintiffs' definition of "Mylan" as overly broad and unduly burdensome. For purposes of these Topics, "Mylan" shall refer solely to Mylan Pharmaceutical Inc. and Mylan Laboratories Inc., named Defendants to this litigation.

8. Mylan objects to Plaintiffs' Topics to the extent that they impose an obligation on Mylan to provide testimony or information that is in the public domain and, therefore, equally accessible to Plaintiffs.

9. Mylan objects to Plaintiffs' Topics to the extent that they call for testimony or information concerning any legal conclusion.

10. Mylan objects to Plaintiffs' Topics as overly broad, unduly burdensome, and not reasonably calculated to lead to the discovery of admissible evidence, particularly to the extent that they seek testimony or information concerning galantamine and/or galantamine products unrelated to Mylan's proposed generic galantamine products under Abbreviated New Drug Application No. 77-590. Requiring Mylan to testify on such Topics would be unduly burdensome on Mylan.

**SPECIFIC OBJECTIONS AND RESPONSES**

**Topic No. 1.**

Mylan's Paragraph IV notice including, without limitation, the meaning of, basis for, and any evaluation or analysis concerning the statement set forth in the letter that the "'318 patent[] will not be infringed by the commercial manufacture, use or sale of the drug products described in Mylan's ANDA and/or such patents are invalid."

**RESPONSE:** Mylan objects to this Topic to the extent that it is directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. Mylan further objects to the extent that this Topic seeks testimony or information concerning infringement/non-infringement. The Defendants have stipulated to infringement, in the event that the patent-in-suit is found valid and enforceable, and therefore infringement/non-infringement is no longer at issue in this litigation. Plaintiffs furthermore agreed in the Stipulation that they "will not seek discovery from Defendants relating solely to the issue of infringement of the '318 patent." Mylan also objects on the ground that the referenced statement involves patents not at issue in this litigation. In addition, Mylan objects to this Topic on the grounds that it is overly broad, unduly burdensome and seeks testimony or information that is not reasonably calculated to lead to the discovery of admissible evidence. Mylan further objects on the ground that this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege. Mylan also objects to the extent that this Topic is cumulative and duplicative of other Topics in the Rule 30(b)(6) notices served to Mylan, including Topic 15 herein.

**Topic No. 2.**

Any evaluation, consideration or discussion conducted by Mylan to develop the Generic Product, including the names and responsibilities of all persons who were involved in the evaluation, consideration or discussion by Mylan to develop the Generic Product.

**RESPONSE:** Mylan objects to this Topic to the extent that it is directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. Mylan further objects to this Topic on the grounds that it is overly broad, unduly burdensome and seeks testimony or information that is not reasonably calculated to lead to the discovery of admissible evidence. This Topic seeks testimony or information on “any evaluation, consideration or discussion,” including the identities of “all persons” who were involved. Mylan also objects on the ground that this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege. Mylan further objects to the extent that this Topic is cumulative and duplicative of other Topics in the Rule 30(b)(6) notices served to Mylan, including Topics 11 and 12 herein.

**Topic No. 3.**

The decision to file an application with the FDA seeking approval to manufacture and sell a drug product containing galantamine.

**RESPONSE:** Mylan objects to this Topic to the extent that it is directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. Mylan further objects to the extent that this Topic seeks testimony or information concerning any galantamine product that is not subject to Mylan’s ANDA No. 77-590. Plaintiffs have refused to provide similar information concerning other drug products containing galantamine. Also, based on Plaintiffs’ letter dated March 10, 2006, Plaintiffs have agreed to limit discovery only to that which relates “to the specific products that are the subject of Janssen’s New Drug Application . . . 21-169 and the defendants’ Abbreviated New Drug

Applications . . . .” (3/10/06 Letter from K. Calia at 1). Mylan also objects to this Topic on the grounds that it is overly broad, unduly burdensome and seeks testimony or information that is not reasonably calculated to lead to the discovery of admissible evidence. In addition, Mylan objects on the ground that this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege. Mylan further objects to the extent that this Topic is cumulative and duplicative of other Topics in the Rule 30(b)(6) notices served to Mylan, including Topic 2 herein.

**Topic No. 4.**

Any evaluation, consideration or discussion conducted by Mylan to market the Generic Product, including the names and responsibilities of all persons who were involved in the evaluation, consideration or discussion by Mylan to market the Generic Product.

**RESPONSE:** Mylan objects to this Topic to the extent that it is directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. Mylan further objects to this Topic on the grounds that it is overly broad, unduly burdensome and unlimited in time and/or scope. This Topic seeks testimony or information on “all persons” involved in the “evaluation, consideration or discussion.” Mylan also objects to this Topic as premature to the extent that FDA has not yet approved Mylan’s ANDA 77-590, and therefore Mylan has not started marketing the galantamine product that is the subject of that ANDA. In addition, Mylan objects to the extent that this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege. Mylan further objects to the extent that this Topic is cumulative and duplicative of other Topics in the Rule 30(b)(6) notices served to Mylan, including Topic 6 herein.

**Topic No. 5.**

The benefits, including revenues and profits, that Mylan projects, anticipates, expects, or forecasts it will obtain should Mylan's ANDA receive approval from the U.S. Food and Drug Administration.

**RESPONSE:** Mylan objects to this Topic on the grounds that it seeks testimony or information that is not reasonably calculated to lead to the discovery of admissible evidence. Mylan further objects to this Topic on the grounds that it is overly broad and unduly burdensome. Mylan also objects to this Topic as premature to the extent that FDA has not yet approved Mylan's ANDA 77-590, and therefore Mylan has not started marketing the galantamine product that is the subject of that ANDA. In addition, Mylan objects to the extent that this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege.

**Topic No. 6.**

Marketing strategies, marketing plans, and projected sales for Mylan's Generic Product.

**RESPONSE:** Mylan objects to this Topic on the grounds that it seeks testimony or information that is not reasonably calculated to lead to the discovery of admissible evidence. Mylan further objects to this Topic on the grounds that it is overly broad and unduly burdensome. Mylan also objects to this Topic as premature to the extent that FDA has not yet approved Mylan's ANDA 77-590, and therefore Mylan has not started marketing the galantamine product that is the subject of that ANDA. In addition, Mylan objects to the extent that this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege. Mylan further objects to the extent that this Topic is cumulative and duplicative of other Topics in the Rule 30(b)(6) notices served to Mylan, including Topic 4 herein.

**Topic No. 7.**

Each and every contribution and/or input that Mylan, or any employee or agent of Mylan, has made to the preparation, decision to file, filing and/or prosecution of Mylan's ANDA, including: (a) any information relating to regulatory procedures and strategies for obtaining regulatory approval of the Generic Product of Mylan's ANDA; (b) any information comprising, relating to or contained in the 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certifications submitted in connection with Mylan's ANDA; and (c) any information comprising, relating to or contained in the statements of factual and legal basis for invalidity, unenforceability, and/or noninfringement included with the notice of these certifications.

**RESPONSE:** Mylan objects to this Topic to the extent that it is directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. Mylan further objects to the extent that this Topic seeks testimony or information concerning infringement/non-infringement. The Defendants have stipulated to infringement, in the event that the patent-in-suit is found valid and enforceable, and therefore infringement/non-infringement is no longer at issue in this litigation. Plaintiffs furthermore agreed in the Stipulation that they "will not seek discovery from Defendants relating solely to the issue of infringement of the '318 patent." Mylan also objects on the ground that this Topic seeks testimony and information not reasonably calculated to lead to the discovery of admissible evidence. In addition, Mylan objects to this Topic as overly broad, unduly burdensome and unlimited in time and/or scope. Plaintiffs seek testimony or information concerning "each and every contribution and/or input" by "any" employee or agent of Mylan. Mylan further objects to the extent that this Topic is directed to contentions, which information should be sought through interrogatories. Mylan also objects to the extent that this Topic purports to seek expert discovery. Mylan also objects on the grounds that this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege. Mylan objects on the ground that this Topic seeks testimony or information concerning patents not at issue in this litigation. Mylan objects to the extent that this Topic is



cumulative and duplicative of other Topics in the Rule 30(b)(6) notices served to Mylan, including Topic 3 herein.

**Topic No. 8.**

The factual basis for Mylan's proposed assertion that its ANDA is indicated for the treatment of mild to moderate Alzheimer's disease.

**RESPONSE:** Mylan objects to the extent that this Topic seeks testimony or information concerning infringement/non-infringement. The Defendants have stipulated to infringement, in the event that the patent-in-suit is found valid and enforceable, and therefore infringement/non-infringement is no longer at issue in this litigation. Plaintiffs furthermore agreed in the Stipulation that they "will not seek discovery from Defendants relating solely to the issue of infringement of the '318 patent." Mylan further objects to the extent that this Topic seeks testimony or information not reasonably calculated to lead to the discovery of admissible evidence. Mylan also objects to the extent this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege.

**Topic No. 9.**

The circumstances in which Mylan first became aware of galantamine as a treatment for Alzheimer's disease, including but not limited to the date in which this occurred and the people involved.

**RESPONSE:** Mylan objects to this Topic to the extent that it is directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. Mylan further objects to this Topic on the grounds that it is vague and ambiguous, particularly to the extent that it seeks testimony or information on "the people involved," and not reasonably calculated to lead to the discovery of admissible evidence. Mylan also objects on the grounds that this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege.

**Topic No. 10.**

The circumstances in which Mylan first became aware of the '318 patent, including but not limited to the date in which this occurred and the people involved.

**RESPONSE:** Mylan objects to this Topic to the extent that it is directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. Mylan further objects to this Topic on the grounds that it is vague and ambiguous, particularly to the extent that it seeks testimony or information on “the people involved,” and not reasonably calculated to lead to the discovery of admissible evidence. Mylan also objects on the grounds that this Topic seeks testimony and information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege.

**Topic No. 11.**

Any consideration or evaluation to develop a drug product containing galantamine for the treatment of Alzheimer’s disease conducted by or on behalf of Mylan.

**RESPONSE:** Mylan objects to this Topic to the extent that it is directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. Mylan further objects to this Topic on the grounds that it is overly broad, unduly burdensome and seeks testimony or information that is not reasonably calculated to lead to the discovery of admissible evidence. Mylan also objects to the extent that this Topic seeks testimony or information concerning any galantamine product that is not subject to Mylan’s ANDA No. 77-590. Plaintiffs have refused to provide similar information concerning other drug products containing galantamine. Also, based on Plaintiffs’ letter dated March 10, 2006, Plaintiffs have agreed to limit discovery only to that which relates “to the specific products that are the subject of Janssen’s New Drug Application . . . 21-169 and the defendants’ Abbreviated New Drug Applications . . . .” (3/10/06 Letter from K. Calia at 1). In addition, Mylan objects on the grounds that this Topic seeks testimony and information protected by the attorney-client

privilege, attorney work product and/or any other applicable privilege. Mylan further objects to the extent that this Topic is cumulative and duplicative of other Topics in the Rule 30(b)(6) notices served to Mylan, including Topic 2 herein.

**Topic No. 12.**

Identification of all individuals, whether employees of Mylan or third parties, having a role in consideration or evaluation by Mylan of developing a drug product containing galantamine for the treatment of Alzheimer's disease that is the subject of Topic 10.

**RESPONSE:** Mylan objects to this Topic to the extent that it is directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. Mylan further objects to this Topic on the grounds that it is overly broad, unduly burdensome and seeks testimony or information that is not reasonably calculated to lead to the discovery of admissible evidence. This Topic seeks testimony or information on "all individuals," including third parties, "having a role in consideration or evaluation." Mylan also objects to the extent that this Topic seeks testimony or information concerning any galantamine product that is not subject to Mylan's ANDA No. 77-590. Plaintiffs have refused to provide similar information concerning other drug products containing galantamine. Also, based on Plaintiffs' letter dated March 10, 2006, Plaintiffs have agreed to limit discovery only to that which relates "to the specific products that are the subject of Janssen's New Drug Application . . . 21-169 and the defendants' Abbreviated New Drug Applications . . . ." (3/10/06 Letter from K. Calia at 1). In addition, Mylan objects on the ground that this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege. Mylan further objects to the extent that this Topic is cumulative and duplicative of other Topics in the Rule 30(b)(6) notices served to Mylan, including Topics 2 and 11 herein. Mylan incorporates herein any other objection asserted in response to Topic 10.

**Topic No. 13.**

Any effort to develop any drug product other than the Generic Product set forth in Mylan's ANDA for the treatment of Alzheimer's disease conducted by or on behalf of Mylan.

**RESPONSE:** Mylan objects to this Topic on the grounds that it is overly broad, unduly burdensome and seeks testimony or information that is not reasonably calculated to lead to the discovery of admissible evidence. Mylan further objects to the extent that this Topic seeks testimony or information concerning any galantamine product that is not subject to Mylan's ANDA No. 77-590. Plaintiffs have refused to provide similar information concerning other drug products containing galantamine. Also, based on Plaintiffs' letter dated March 10, 2006, Plaintiffs have agreed to limit discovery only to that which relates "to the specific products that are the subject of Janssen's New Drug Application . . . 21-169 and the defendants' Abbreviated New Drug Applications . . . ." (3/10/06 Letter from K. Calia at 1). Mylan also objects on the grounds that this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege.

**Topic No. 14.**

Identification of all individuals, whether employees of Mylan or third parties, having a role in the research, development or testing of such a treatment responsive to Topic 12 and a description of those roles.

**RESPONSE:** Mylan objects to this Topic on the grounds that it is overly broad and unduly burdensome. Plaintiffs seek testimony identifying "all individuals," including third parties, and a description of any role of any of these individuals. Mylan further objects to this Topic to the extent that it seeks information not within the possession, custody or control of Mylan. Mylan also objects to the extent that this Topic is vague and ambiguous, particularly to the extent that it seeks the identity of individuals having a role in the research, development or

testing “of such a treatment responsive to Topic 12.” Mylan incorporates herein any other objection asserted in response to Topic 12.

**Topic No. 15.**

The factual and legal bases for Mylan’s Second Defense (invalidity).

**RESPONSE:** Mylan objects to this Topic to the extent that it is directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. Mylan further objects to the extent that this Topic is directed to contentions, which information should be sought through interrogatories. Mylan also objects to the extent that this Topic purports to seek expert discovery. In addition, Mylan objects to the extent any information sought is in the possession, custody or control of Plaintiffs. Mylan further objects on the ground that this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege. Mylan also objects to the extent that this Topic is cumulative and duplicative of other Topics, including Topic 16 herein.

**Topic No. 16.**

The factual and legal bases for Mylan’s Second Claim for Relief (declaratory judgment of invalidity) according to its proof elements, including an element-by-element comparison of each asserted claim of the ‘318 patent to the prior art Mylan relies upon and the motivation of one of skill in the art to combine any references under 35 U.S.C. § 103, as well as a description of any non-prior art defenses such as lack of enablement, insufficient written description, failure to disclose best mode, or claim indefiniteness under 35 U.S.C. § 112.

**RESPONSE:** Mylan objects to this Topic to the extent that it is directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. Mylan further objects to the extent that this Topic is directed to contentions, which information should be sought through interrogatories. Mylan also objects to the extent that this Topic purports to seek expert discovery. In addition, Mylan objects to the extent any information sought is in the possession, custody or control of Plaintiffs. Mylan further objects

on the ground that this Topic seeks testimony or information protected by the attorney-client privilege, attorney work product and/or any other applicable privilege. Mylan also objects to the extent that this Topic is cumulative and duplicative of other Topics in the Rule 30(b)(6) notices served to Mylan, including Topic 15 herein.

**Topic No. 17.**

The identity and location of documents and things concerning the foregoing topics.

**RESPONSE:** Mylan objects to the extent that this Topic is overly broad and unduly burdensome. Mylan further objects to the extent that this Topic seeks testimony, documents or information protected by the attorney-client privilege, the attorney work product doctrine and/or any other applicable privilege and/or documents. Mylan also objects to the extent that this Topic seeks testimony or information directed to willful infringement, which claim the Court dismissed and, therefore, which is no longer at issue in this litigation. In addition, Mylan objects to the extent that this Topic seeks testimony or information concerning infringement/non-infringement. The Defendants have stipulated to infringement, in the event that the patent-in-suit is found valid and enforceable, and therefore infringement/non-infringement is no longer at issue in this litigation. Plaintiffs furthermore agreed in the Stipulation that they “will not seek discovery from Defendants relating solely to the issue of infringement of the ‘318 patent.”

**Topic No. 18.**

Mylan’s document retention policies from 1986 to the present.

**RESPONSE:** Mylan objects to the extent that this Topic seeks testimony or information that is not reasonably calculated to lead to the discovery of admissible evidence.

**Topic No. 19.**

Persons knowledgeable about the subject matter of the foregoing topics.

**RESPONSE:** Mylan objects to the extent that this Topic is overly broad and unduly burdensome. Mylan further incorporates in its Response to Topic 19 its objections to the other Topics herein.



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*Attorneys for Mylan Pharmaceuticals Inc.  
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Dated: March 13, 2006

**CERTIFICATE OF SERVICE**


It is hereby certified this 13<sup>th</sup> day of March, 2006 that copies of the foregoing document, **MYLAN PHARMACEUTICALS INC.'S AND MYLAN LABORATORIES INC.'S RESPONSES AND OBJECTIONS TO PLAINTIFFS' NOTICE OF DEPOSITION UNDER FED. R. CIV. P. 30(b)(6) (with noticed deposition date of March 15, 2006)**, were served on counsel as indicated:

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